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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/526,065 | 04/08/2005 | Takaaki Terahara | 7388/84280 | 6606 |
| 20529 7590 01/29/2008 NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314 | | | EXAMINER ELLIS, SUEZU Y | |
| | | | ART UNIT 1615 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,065

Applicant(s)

TERAHARA ET AL.

Examiner

Suezu Ellis

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/28/05, 4/8/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on February 28, 2005 and April 8, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terahara et al. (CA 2428181).

With respect to claims 1, 5-7 and 9, Terahara et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and pergolide and/or a pharmaceutically acceptable salt thereof (pg. 17, lines 9-12; pg. 9, lines 23-24), wherein the adhesive layer comprises an acrylic polymer being a copolymer that includes butyl acrylate or methyl methacrylate (pg. 14, lines 8-9), therefore is considered to be having self-adhesion properties as well as being substantially free of carboxyl and hydroxyl groups, and a rubber polymer (SIS) (pg. 13, lines 15-18). Terahara et al. also discloses the acrylic polymer being 10-40% by weight and the rubber polymer being 20-40% by weight (pg. 13, line 24 – pg. 14, line 17).

Terahara et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:1 to 1:9. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be fall between 1:1 and 1:9. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to create an adhesive layer having good permeability of the drug (pg. 14, lines 16-17). Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 2 and 3, the modified Terahara et al. discloses the adhesive base agent further comprises a basic nitrogen-including polymer including a

basic nitrogen (pg. 6, lines 3-9). The modified Terahara et al. discloses the basic nitrogen-including polymer being a methyl methacrylate – butyl methacrylate – dimethylaminoethyl methacrylate terpolymer, or polyvinyl acetal diethylamino acetate. (pg. 6, lines 24-25). The modified Terahara et al. further illustrates in Example 5, a formulation having pergolide mesilate that includes a an acrylate polymer, a rubber (SIS) and a basic nitrogen-including polymer, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1. It would have been obvious to one of ordinary skill in the art to modify the amount of basic nitrogen-including polymer in order to enhance the skin permeability of the drug (pg. 4, line 21 – pg. 5, line 9). Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 4, the modified Terahara et al. discloses the adhesive layer comprising an alicyclic saturated hydrocarbon resin-based tackifier (pg. 14, lines 18-24). The modified Terahara et al. further illustrates in Example 5, a formulation having pergolide mesilate that includes an acrylate polymer, a rubber (SIS) and alicyclic saturated hydrocarbon resin, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the alicyclic saturated hydrocarbon resin is from 9:1 to 1:1. It would have been obvious to one of ordinary skill in the art to modify the amount of tackifier in order to provide the desired amount of adhesion with the consideration of irritation to the skin at a peeling time (pg. 15, lines 6-11). Further,

since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 10 and 11, the modified Terahara et al. discloses the adhesive agent further comprises an organic acid (acetic acid) (pg. 8, lines 18-20).

Claims 1 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (EP 1 201 232) in view of Hirano et al. (US 2002/0102290).

With respect to claims 1 and 5-9, Chono et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and pergolide and/or a pharmaceutically acceptable salt thereof [0014], [0015], wherein the adhesive layer comprises an acrylic polymer being a copolymer that includes 2-ethylhexyl acrylate and vinyl acetate [0030], therefore is considered to be having self-adhesion properties as well as being substantially free of carboxyl and hydroxyl groups, and a rubber polymer (SIS) [0030], [0031]. Chono et al. also discloses the acrylic polymer being 10-98% by weight and the rubber polymer being 10-60% by weight [0031]. Chono et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:1 to 1:9. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be fall between 1:1 and 1:9. Further, Hirano et al. demonstrates in Example 1, a pressure-sensitive adhesive comprising an acrylate polymer (2-ethylhexyl acrylate-vinyl acetate copolymer) and a rubber polymer

(polyisobutylene and styrene/isoprene/styrene block copolymer), wherein the weight ratio of acrylic polymer to rubber polymer is 1:2. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to create an adhesive layer having good permeability of the drug [0031]. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 4, the modified Chono et al. discloses the adhesive layer comprising an alicyclic saturated hydrocarbon resin-based tackifier [0032]. The modified Chono et al. discloses the tackifier being from 10-70% by weight of the total composition of the adhesive layer, therefore demonstrating the ability to attain a weight ratio of the total content of acrylic polymer and rubber polymer to the content of the tackifier being from 1:1 to 1:9. It would have been obvious to one of ordinary skill in the art to modify the amount of tackifier in order to provide the desired amount of adhesion with the consideration of irritation to the skin at a peeling time [0032]. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 10 and 11, the modified Chono et al. discloses the adhesive agent comprises an organic acid (acetic acid) [0017].

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Hirano et al. and further in view of Terahara et al.

With respect to claims 2 and 3, the modified Chono et al. addresses all the limitations of claim 1, however fails to expressly disclose the inclusion of a basic nitrogen-including polymer that includes a basic nitrogen and having no self-adhesion property, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1. Terahara et al. discloses a patch having a basic nitrogen-including polymer being a methyl methacrylate – butyl methacrylate – dimethylaminoethyl methacrylate terpolymer, or polyvinyl acetal diethylamino acetate. (pg. 6, lines 24-25). Terahara et al. further illustrates in Example 5, a formulation having pergolide mesilate that includes a an acrylate polymer, a rubber (SIS) and a basic nitrogen-including polymer, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1. It would have been obvious to one of ordinary skill in the art to include a basic nitrogen-including polymer and modify the amount thereof, in order to enhance the skin permeability of the drug, as taught by Terahara et al. (pg. 4, line 21 – pg. 5, line 9).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8 and 12 of copending Application No. 10/469,612 (amendment filed on 10/4/07) in view of Hirano et al.

This is a provisional obviousness-type double patenting rejection.

With respect to claim 1 of the current application, claims 1, 8 and 12 of Application No. 10/469,612 (amended claims filed 10/4/07) discloses:

(claim 1) A patch comprising a support (functionally equivalent to a backing layer), and an adhesive layer laid on the support and containing an adhesive base (adhesive agent) and a drug, wherein said adhesive base contains an acrylic polymer substantially having no carboxyl group and no hydroxyl group in molecules thereof, wherein said polymer is at least one selected from the group consisting of: a 2-ethylhexyl acrylate N-vinyl-2-pyrrolidone 1,6-hexane glycol dimethacrylate copolymer;

an aminoalkylmethacrylate copolymer E; and a 2-ethylhexyl acrylate vinyl copolymer;
and a rubber-based polymer.

(claim 8) wherein said drug is at least one selected from the group consisting of pergolide, pharmacologically acceptable salts of pergolide, oxybutynin, and pharmacologically acceptable salts of oxybutynin.

(claim 12) wherein said drug is selected from the group consisting of pergolide and pharmaceutically acceptable salts of pergolide.

Claims 1, 8 and 12 of Application No. 10/469,612 fail to expressly disclose the weight ratio of content of the acrylic polymer to content of the rubber polymer being from 1:1 to 1:9. Hirano et al. demonstrates in Example 1, a pressure-sensitive adhesive comprising an acrylate polymer (2-ethylhexyl acrylate-vinyl acetate copolymer) and a rubber polymer (polyisobutylene and styrene/isoprene/styrene block copolymer), wherein the weight ratio of acrylic polymer to rubber polymer is 1:2. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to create an adhesive layer having good permeability of the drug. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Telephone/Fax Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE


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